



Press Release

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GREER® Laboratories, Inc. Launches ORALAIR®, the First and Only Sublingual Allergy Immunotherapy Tablet with a Mix of Five Grass Allergens for the Treatment of Grass Pollen Allergy

ORALAIR (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Tablet for Sublingual Use Now Available in the U.S.

LENOIR, N.C. – May 5, 2014 – [GREER® Laboratories, Inc.](http://www.greerlab.com), a leading developer and provider of allergy immunotherapy products and services, today announced the launch and commercial availability of ORALAIR® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) sublingual allergy immunotherapy tablet. ORALAIR is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product. ORALAIR is approved for use in persons 10 through 65 years of age. ORALAIR is not indicated for the immediate relief of allergy symptoms.

Grass allergies are the most common seasonal allergy in the United States^{1,2} and most people are allergic to more than one type of grass.³ ORALAIR is the first and only FDA approved oral allergy immunotherapy tablet that includes a five grass, mixed pollens allergen extract. These grasses are widely distributed throughout the U.S.

“We are pleased to now be able to supply ORALAIR which provides an additional option for treating grass allergies in the U.S. and helps to fill a current unmet need in allergy patient care,” said John G. Roby, GREER president and CEO. “Grass allergies affect millions of people, however we know that many patients who are candidates for immunotherapy refuse or discontinue allergy injections. GREER’s commitment to allergy innovation is guided by our desire to provide support to allergy specialists and relief to patients through immunotherapy.”

ORALAIR is taken for about four months before the expected start of the grass pollen season and is continued throughout the grass pollen season. ORALAIR is a tablet that dissolves under the tongue. The first dose is taken in the allergy specialist’s office under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions. The patient will be observed for at least 30 minutes for symptoms of serious allergic reactions. If the patient tolerates the first dose, the remaining doses are administered once a day by the patient or the patient’s caregiver.

ORALAIR reduces grass allergy symptoms for patients within the first allergy season that it is taken. ORALAIR is not indicated for the immediate relief of allergy symptoms. The prescribing information for ORALAIR includes a Boxed Warning regarding severe allergic reactions.

ORALAIR also provides significant symptom relief for the long term. In a five-year, multicenter clinical trial of 426 adults in 10 European countries, efficacy was sustained during three years of treatment and ORALAIR significantly reduced daily Combined Score (CS) compared with placebo during every year of treatment. Data were insufficient to demonstrate efficacy for one or two years after discontinuation of ORALAIR.

The ORALAIR clinical program was based on safety, efficacy and tolerability results from an extensive set of clinical trials which included, in both the United States and Europe, over 2,500 adults and children. ORALAIR was generally well tolerated and the most common adverse events (reported in $\geq 5\%$ of patients) were oral pruritus, throat irritation, ear pruritus, mouth edema, tongue pruritus, cough and oropharyngeal pain.

GREER relies on a network of specialty pharmacies that fulfill ORALAIR prescriptions and mail the medication directly to patients. When patients receive the first dose of ORALAIR in their allergy specialist's office, they will also receive a starter pack as well as a brochure containing information about the ORALAIR Co-Pay Assistance Program and All-Points Allergy™ Patient Support Program. The ORALAIR Co-Pay Assistance Program can be accessed by visiting www.ORALAIR.com.

Please see full Prescribing Information at <http://oralair.com/docs/ORALAIR%20Prescribing%20Information-Med%20Guide.pdf> including Boxed Warning and Medication Guide at <http://oralair.com/docs/ORALAIR%20Med%20Guide.pdf>.

GREER holds exclusive U.S. commercialization rights to ORALAIR through its partnership with STALLERGENES, developer and manufacturer of the product.

For more information on ORALAIR, visit www.ORALAIR.com.

About ORALAIR®

ORALAIR was originally approved in Europe in 2008 and is currently authorized in 31 countries around the world including most European countries, U.S., Canada, Australia, and Russia for the treatment of grass pollen allergy. In Canada, ORALAIR® was launched in 2012, making it the first allergy immunotherapy tablet to be registered and marketed in North America. World-wide post-marketing experience with ORALAIR® includes more than 20 million doses given to more than 110,000 patients.

ORALAIR has been approved based on results from an extensive clinical development program. ORALAIR® has been studied in double-blind, placebo-controlled trials, in both Europe and the United States in over 2,500 adults and children. Positive results were achieved in these trials designed to demonstrate that pre-seasonal and co-seasonal treatment with grass allergy immunotherapy reduces patients' allergy symptoms and their need for symptom-relieving medication.

Important Safety Information

WARNING: SEVERE ALLERGIC REACTIONS

ORALAIR can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema. Do not administer ORALAIR to patients with severe, unstable or uncontrolled asthma. Observe patients in the office for at least 30 minutes following the initial dose. Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use. ORALAIR may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. ORALAIR may not be suitable

for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

ORALAIR is contraindicated in patients with severe, unstable or uncontrolled asthma, patients with a history of any severe systemic allergic reaction or severe local reaction to sublingual allergen immunotherapy, or patients who are hypersensitive to any of the inactive ingredients.

ORALAIR can cause systemic allergic reactions, including anaphylaxis, and severe local reactions, including laryngopharyngeal swelling, which may be life-threatening. Severe and serious allergic reactions may require treatment with epinephrine. Patients who have a systemic allergic reaction to ORALAIR should stop taking the product. ORALAIR treatment should be withheld if the patient is experiencing an acute asthma exacerbation. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of ORALAIR. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.

In case of oral inflammation or wounds, such as following oral surgery or dental extraction, ORALAIR treatment should be discontinued to allow complete healing of the oral cavity.

The most common adverse events reported in $\geq 5\%$ of patients were oral pruritus, throat irritation, ear pruritus, mouth edema, tongue pruritus, cough, and oropharyngeal pain. Patients who have escalating or persistent local reactions to ORALAIR should be reevaluated and considered for discontinuation of ORALAIR.

ORALAIR should be used during pregnancy or breastfeeding only if clearly needed.

About STALLERGENES

STALLERGENES is a global healthcare company specialized in the diagnosis and treatment of allergies. For more than 50 years, it has been continuously expanding the existing frontiers of science in order to provide allergy patients with more effective long lasting therapeutic options. Thanks to its innovation strategy, fueled by investments amounting to around 20% of total annual revenues as well as external cooperations, STALLERGENES is able to provide targeted allergen immunotherapy-based allergy solutions that significantly improve the lives of allergy patients around the world.

STALLERGENES operates in 20 countries and employs over 1,000 people. In 2013, the Company generated total revenues of €248 million, and more than 500,000 patients were treated with STALLERGENES products.

Euronext Paris (Compartment B)
CAC small
ISIN: FR0000065674
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Additional information is available at <http://www.stallergenes.com>

About GREER®

GREER® is a leading developer and provider of allergy immunotherapy products and services for treating humans and animals. As part of its commitment to allergy immunotherapy innovation, GREER's clinical development programs are focused on sublingual allergy immunotherapy liquid (SAIL)™. GREER will also market ORALAIR®, a sublingual allergy immunotherapy tablet with a mix of five grass allergen extracts, in the United States through its partnership with

STALLERGENES. Sublingual immunotherapy is an extension of GREER's allergy immunotherapy products and provides another treatment option for allergy specialists to offer patients.

GREER was founded in 1904 and is located in Lenoir, North Carolina. For more information, visit www.greerlabs.com.

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¹ Salo PM, Calatroni A, Gergen PJ, et al. Allergy-related outcomes in relation to serum IgE: results from the National Health and Nutrition Examination Survey 2005-2006. *J Allergy Clin Immunol*. 2011;127(5):1226-1235.

² Arbes SJ Jr, Gergen PJ, Elliott L, Zeldin DC. Prevalences of positive skin test responses to 10 common allergens in the US population: results from the third National Health and Nutrition Examination Survey. *J Allergy Clin Immunol*. 2005;116(2):377-383.

³ Esch RE. Grass pollen allergens. In: Lockey RF, Bukantz SC, eds. *Allergens and Allergen Immunotherapy*. 2nd ed. New York, NY: Marcel Dekker; 1999:103-120.